

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

FRESENIUS KABI USA, LLC,

Plaintiff,

v.

PAR STERILE PRODUCTS, LLC, and  
PAR PHARMACEUTICAL  
COMPANIES, INC.,

Defendants.

No. 2:16-cv-04544 (SDW) (LDW)

**PUBLIC VERSION  
REDACTED**

**Oral Argument Requested**

**DEFENDANTS PAR STERILE PRODUCTS, LLC AND PAR  
PHARMACEUTICAL COMPANIES, INC.'S SUPPLEMENTAL BRIEF ON  
SUMMARY JUDGMENT DISPOSITION**

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## GLOSSARY

ANDA	Abbreviated New Drug Application
API	Active pharmaceutical ingredient
Bachem	Bachem Americas, Inc.
BCN	BCN Peptides
CA3 Op.	Opinion, <i>Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC</i> , No. 20-1618 (3d Cir. Feb. 11, 2021)
DMF	Drug Master File
FK CA3 Br.	Opening Brief of Appellant Fresenius Kabi USA, LLC, <i>Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC</i> , No. 20-1618, Dkt. 23 (3d Cir. June 15, 2020) (filed under seal)
FK CA3 Reply	Reply Brief of Appellant Fresenius Kabi USA, LLC, <i>Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC</i> , No. 20-1618, Dkt. 44 (3d Cir. Oct. 5, 2020) (filed under seal)
Fresenius	Fresenius Kabi USA, LLC
NDA	New Drug Application
<i>Orange Book</i>	<i>Approved Drug Products With Therapeutic Equivalence Evaluations</i> , an FDA publication that lists FDA-approved drug products and any related patents
Par	Par Sterile Products, LLC and Par Pharmaceutical Companies, Inc., collectively
Par CA3 Br.	Answering Brief of Appellee Par Sterile Products, LLC and Par Pharmaceutical Companies, Inc., <i>Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC</i> , No. 20-1618, Dkt. 37 (3d Cir. Aug. 31, 2020) (filed under seal)
PolyPeptide	PolyPeptide Laboratories Sweden AB

POSA	Person of Ordinary Skill in the Art
Vasopressin API	Active pharmaceutical ingredient used in Vasopressin Injection
Vasopressin Injection	Vasopressin solution for intravenous injection

## I. INTRODUCTION

The facts in this case are no more in dispute now than they were when this Court granted Par's motion for summary judgment in 2020. Fresenius still has no path to success, through a *Wellbutrin* patent-law analysis or otherwise.<sup>1</sup> There is still no genuine dispute of material fact on the questions of *antitrust injury* and *substantial foreclosure*, and under well-settled Third Circuit law, this Court should grant summary judgment in Par's favor on either or both grounds. If the Court addresses *causation*, it will find that Fresenius has not presented sufficient evidence to allow a *Wellbutrin* patent-law analysis. But even if the Court conducts that analysis, it is undisputed that Fresenius would not have avoided infringement of Par's patents, and that Fresenius has not presented the clear and convincing evidence necessary to overcome the statutory presumption of patent validity. That failure is an independent reason to grant summary judgment for Par.

Fresenius will insist that the Third Circuit's treatment of *Wellbutrin* requires the Court to conduct a new patent-law analysis. But the material facts are undisputed; no amount of new argument will cure the fatal defects in Fresenius's claims:

- *First*, despite [REDACTED] **Topics C, F** [REDACTED]
- *Second*, exclusive contracts *do not* give rise to antitrust concerns *unless*

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<sup>1</sup> See *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3d Cir. 2017).

they “substantially foreclose” competition in the relevant market. To make that showing, Fresenius must demonstrate that Par locked up “so large a percentage” of the upstream supply of Vasopressin API that competition in the downstream market was unreasonably constricted. Despite Fresenius’s attempt to rewrite established Third Circuit case law, its failure to present evidence on who participated in the API supply market, let alone how much of that market Par allegedly controlled, is fatal.

- ***Finally***, Fresenius cannot establish causation because the record requires layer upon layer of speculation just to determine what Fresenius’s alleged “but-for” product would have been. That ambiguity prevents the Court from analyzing the substance of the patent claims. But even under a *Wellbutrin* patent-law analysis, Fresenius has failed to put forward a cognizable theory of non-infringement or invalidity, relying only on the legally deficient opinions of its patent experts.

There is nothing in the Third Circuit’s opinion suggesting that this Court reached the wrong conclusion in granting summary judgment for Par, or that it should not again reach the same conclusion—whether on the basis of antitrust injury, substantial foreclosure, or causation. None of these issues presented a genuine dispute of material fact in 2020. They still do not today.

## II. PROCEDURAL HISTORY

In February 2020, this Court granted summary judgment for Par on the ground that “Par’s patents cut off the chain of causation,” negating a necessary element of Fresenius’s claims. Dkt. 240 at 12. Fresenius predicted that it *would have* overcome Par’s patents in the “but-for world.” The Court found that theory “unduly speculative” because there was no actual patent litigation to guide Fresenius’s predictions and no ANDA on which to base an infringement analysis. *Id.* at 7–10.



On appeal, the Third Circuit vacated the summary judgment order—but it did *not* hold that this Court reached the wrong conclusion. Just the opposite, the Third Circuit emphasized that this Court may again rule for Par on remand. Pointing out that “no patent analysis is needed” if Par’s exclusive contract with BCN is not anticompetitive, the Third Circuit identified several problems with Fresenius’s ***substantial foreclosure*** theory. CA3 Op. 10–11 n.12. For instance, “there were other API suppliers who were willing to provide API to Fresenius” and “other manufacturers worked with suppliers other than BCN, and those manufacturers eventually filed ANDAs.” *Id.* With respect to ***antitrust injury***, the Third Circuit noted (as this Court did in its prior summary judgment ruling) that Fresenius “was offered the chance to compete for an exclusive arrangement with BCN for its API via a competitive monetary offer but declined to pursue it.” *Id.* (citing *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 79, 84 (3d Cir. 2010)). Consistent with the Third Circuit’s opinion, antitrust injury and substantial foreclosure provide two independent bases for granting summary judgment in Par’s favor.

As for ***causation***, the Third Circuit stated that this Court need “consider the substance of” the parties’ patent arguments *only if* this Court first determines that “the record permits [it] to engage in such an analysis.” CA3 Op. 9–10 (quotation omitted). For example, if there are “ambiguities in what the proposed ANDA would have contained,” “grounds [on which] to reject” a patent expert’s opinions,

or “other deficiencies in the record,” that will “absolve” this Court of conducting a *Wellbutrin* patent-law analysis, requiring dismissal for lack of causation. *Id.* at 9 nn.8–9. But even if a *Wellbutrin* analysis were possible, this Court must still “examine the record to determine whether a reasonable jury could find that Par’s patents would have blocked Fresenius Kabi’s market entry.” *Id.* at 10.

### III. ARGUMENT

On the basis of undisputed material facts, there are three independently sufficient reasons this Court should grant summary judgment for Par.<sup>2</sup> **First**, Fresenius has not suffered any antitrust injury; **Topics C, F**

**[REDACTED]**, an undisputed fact that this Court and the Third Circuit confirmed. **Second**, there is no evidence that Par locked up a sufficiently large percentage of the API supply to substantially foreclose competition—a requirement under well-settled Third Circuit law. **Third**, the record does not permit this Court to engage in a *Wellbutrin* patent-law analysis to assess causation—but even if it could, the undisputed facts lead to the inescapable conclusion that Par’s patents sever the chain of causation. Standing alone, *each* of these failures is fatal.

#### A. Fresenius Did Not Incur Any Antitrust Injury.

The *sine qua non* of any antitrust claim is antitrust injury, a “loss [that]

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<sup>2</sup> The Third Circuit holds that “summary judgment is not disfavored in the antitrust context.” *Race Tires*, 614 F.3d at 73. Rather, an antitrust plaintiff “must overcome a higher threshold.” CA3 Op. 8 n.6 (quoting *Race Tires*, 614 F.3d at 73).

stems from a competition-*reducing* aspect or effect of the defendant’s behavior.”

*Atl. Richfield Co. v. USA Petrol. Co.*, 495 U.S. 328, 344 (1990). While Fresenius also complains about Par’s alleged arrangements with Bachem and PolyPeptide, its theory of antitrust injury focuses on its [REDACTED] **Topics C, F**

[REDACTED]<sup>3</sup> The undisputed facts show that [REDACTED] **Topics C, F**

[REDACTED] is *not* an antitrust injury. *Race Tires*, 614 F. 3d at 83–84.

[REDACTED] **Topics C, F**

[REDACTED].<sup>4</sup> For years, Fresenius [REDACTED] **Topics C, F**

Dkt. 167-23 at 108:6–23. [REDACTED] **Topics C, F**

[REDACTED].  
Dkt. 154-1 ¶¶ 220–42. Failing to top a competitor’s bid can result in lost business, but that is the consequence of competition’s *presence*, not its *absence*.

[REDACTED] **Topics C, F**, FK CA3 Br.

54–55, but as this Court previously found, it “did not bid for[] a semi-exclusive contract with BCN.” Dkt. 240 at 3.<sup>5</sup> [REDACTED] **Topics C, F**

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<sup>3</sup> See FK SJ Opp. 39; FK CA3 Br. 14; *see also* Par SJ Reply 11.

<sup>4</sup> Dkt. 167-20 at 131:24–132:13; Dkt. 170-01.

<sup>5</sup> See Dkt. 167-20 at 126:10–128:5, 128:24–129:8; Dkt. 167-09 at 200:18–202:7.

**Topics C, F**.<sup>6</sup> As this Court found, **Topics C, F**

that it did not want “to get into a bidding war” and “would be in position to recognize and respect any type of exclusive arrangements” between BCN and Par. Dkt. 240 at 8 & n.8. As the Third Circuit noted, Fresenius “was offered the chance to compete for an exclusive arrangement with BCN for its API via a competitive monetary offer but declined to pursue it.” CA3 Op. 10 n.12.

**Topics C, F** In *Race Tires*, for instance, the plaintiff alleged that the defendant’s exclusive deals with sanctioning bodies were anticompetitive. 614 F.3d at 63, 78. But the plaintiff, too, had a “clear opportunity to compete” for contracts with the sanctioning bodies. *Id.* at 84. Because the plaintiff had that opportunity, the Third Circuit held, it “never suffered the kind of injury that gives rise to an antitrust claim.” *Id.*

Fresenius has tied itself in knots trying to avoid *Race Tires*, but it has never proffered any excuse that is supported by fact and law. *First*, Fresenius asserts that “*Race Tires* is inapplicable when a monopolist coerces exclusivity.” FK CA3 Reply 21. But the defendant in *Race Tires* had substantial monopoly power, *see* 614 F.3d at 62, and the Third Circuit rejected the very argument Fresenius makes here:

**Topics C, F** In *Race*

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<sup>6</sup> Dkt. 179 at 117–18; *see* Dkt. 170-11; Dkt. 167-20 at 126:19–127:18.

*Tires*, the defendant not only paid huge sums of money for exclusivity, it also made a “significant payment . . . to pay off a court judgment” against a sanctioning body. *Id.* at 66, 78–79. Affirming summary judgment for the defendant, the Third Circuit held that “it is no more an act of coercion, collusion, or improper interference . . . to offer more money to the sanctioning body than it is for such suppliers to offer the lowest tire prices.” *Id.* at 79.<sup>7</sup>

Fresenius has tried repeatedly to analogize this case to *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254 (3d Cir. 2012), and *United States v. Dentsply International, Inc.*, 399 F.3d 181 (3d Cir. 2005), in which the Third Circuit found evidence of coercion. Those cases do not apply here. In *ZF Meritor*, Eaton imposed “unfavorable terms,” including “financial penalties,” on OEMs that resisted its demands. 696 F.3d at 266, 277, 285. Likewise, in *Dentsply*, the defendant was able to “impose[]” onerous terms, including “aggressive price increases,” without distributors jumping ship. 399 F.3d at 184–85, 191, 194–96. These heavy-handed tactics stand in stark contrast to Fresenius’s accusation that

Topics C, F

FK SJ Opp. 36; *see* FK CA3 Br. 1–2,

<sup>7</sup>

Topics C, F

FK CA3 Br. 9; *see* Par SJ Reply 15–16; Par CA3 Br. 11.

Topics C, F

Dkt. 151-22.

Topics C, F

FK SJ Opp. 12. Under *Race Tires*, that is competition, not coercion. 614 F.3d at 79.

10. Accepting Fresenius’s proposed analogies would require this Court to radically and unjustifiably reinterpret Third Circuit precedent.

*Second*, Fresenius insists that **Topics C, F**

” FK CA3

Br. 54; FK CA3 Reply 21–22. Even if that were true, it is immaterial; the antitrust laws guarantee only an “opportunity to compete,” *Race Tires*, 614 F.3d at 84, not a right to *win* the competition, *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 116 (1986). **Topics C, F**

— **Topics C, F**

FK CA3 Reply 21. Fresenius is just describing competition. It is no different from *Race Tires*, where the plaintiff proposed “non-exclusivity” but a sanctioning body accepted the defendant’s offer of exclusivity. 614 F.3d at 68.

*Third*, Fresenius claims (with no contemporaneous evidence) that **Topics C, F**

**Topics C, F**

FK

CA3 Br. 53; FK CA3 Reply 22. Of course, this excuse does not explain why

**Topics C, F**

. It also overlooks that “[e]xclusive dealing agreements are often entered into for entirely procompetitive reasons, and generally pose little threat to competition.” *ZF Meritor*, 696 F.3d at 270. As the Third Circuit observed, Fresenius itself has entered exclusive supply agreements. CA3

Op. 10 n.12.<sup>8</sup> In any case, witnesses’ *post hoc* legal opinions do not create a factual dispute. *See Murphy v. Mo. Dep’t of Corr.*, 372 F.3d 979, 982 (6th Cir. 2009).

**Topics C, F**; an “ethical canon” is “not a reason, cognizable under the Sherman Act, for doing away with competition.” *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 696 (1978). Fresenius has not presented *any* case holding that a plaintiff suffers antitrust injury where it is free to compete, **Topics C, F**.<sup>9</sup>

Fresenius has not shown and cannot show antitrust injury. Summary judgment should be granted in Par’s favor.

**B. Fresenius Has Not Created A Genuine Dispute That Par Substantially Foreclosed Competition.**

Fresenius has resisted at every turn its obligation to prove that Par’s alleged exclusive agreements substantially foreclosed access to Vasopressin API.<sup>10</sup> But resistance does not eliminate the requirement. As the Third Circuit recognized here, an “exclusivity agreement is unlawful under the rule of reason only if the probable effect of the arrangement is to substantially lessen competition, rather than merely

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<sup>8</sup> *See, e.g.*, Dkt. 167-20 at 72:14–75:21; Dkt. 167-23 at 17:20–21:10.

<sup>9</sup> *See United States v. Line Material Co.*, 333 U.S. 287, 309–10 (1948) (Sherman Act requires competition “despite any social effect of cutthroat competition on producers and consumers”).

<sup>10</sup> *See, e.g.*, FK SJ Opp. 24 (arguing, wrongly, that “an analysis of market foreclosure is *not* required . . . to survive summary judgment”); FK CA3 Reply 22 (arguing, wrongly, that “calculating the foreclosure percentage is not necessary”).

disadvantage rivals.” CA3 Op. 10–11 n.12 (quotation omitted). The Third Circuit instructed that Fresenius *must* show that “Par ‘foreclose[d] so large a percentage of the available supply’ as to present a threat to competition, not just disadvantage to a rival.” *Id.* (quoting *ZF Meritor*, 696 F.3d at 271, 284). Fresenius has not put forward any evidence that would allow a jury to make that finding, but instead asks this Court to rewrite long-established Third Circuit precedent.

Fresenius did not even *try* to estimate a foreclosure percentage. **Topic I**–

## **Topic I**

. Dkt. 169-30 at 159:2–9, 293:15–19.

## **Topic I**

, a jury would be unable to determine what “percentage of the available supply” Par foreclosed. CA3 Op. 11 n.12 (quotation omitted). Fresenius suggests that it does not have to “define a *second* market [for] vasopressin API.” FK CA3 Reply 26. **Topic I**

Fresenius cannot demonstrate, even in rough terms, what percentage of API Par allegedly controlled—making it impossible to evaluate foreclosure and requiring summary judgment for Par.<sup>11</sup> Fresenius may seek refuge in *LePage’s*, *Dentsply*, and *ZF Meritor*, but it fundamentally misconstrues those cases; unlike Fresenius, the plaintiffs there

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<sup>11</sup> See *Areeda & Hovenkamp*, *Antitrust Law* ¶ 1803a (2020 supp.) (in exclusive-dealing cases, there is no “anticompetitive threat” unless “the defendant has a significant position in both the upstream and downstream markets”).



presented actual evidence of the extent of market foreclosure.<sup>12</sup>

Fresenius may argue that only BCN, Bachem, and PolyPeptide “count,” since they were the only ones with DMFs in 2015–2016. The Third Circuit saw through that assertion, emphasizing that “the absence or presence of a DMF is not in itself dispositive.” CA3 Op. 11 n.12. Since a “DMF need not be finalized until the drug application is filed,” a “manufacturer need not partner with a supplier with an active DMF during its development of an ANDA.” *Id.* at 4 n.2, 11 n.12. Topics C, F

Topics A, C, F . See Dkt. 201-00 at 89:25–90:7; Dkt. 170-17. Topics A, C, F

[REDACTED].<sup>13</sup> The Third Circuit aptly observed that “there were other API suppliers who were willing to provide API to Fresenius,” Topics A, C, F . CA3 Op. 5–6, 10 n.12.

Fresenius downplays these willing API suppliers, arguing that access to a DMF is a “‘critical’ path to the market.” FK SJ Opp. 31. Fresenius again misreads the Third Circuit’s foreclosure cases. In *Dentsply*, the evidence showed that direct sales to consumers—the proposed alternative to Dentsply’s dealer network—was

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<sup>12</sup> Par SJ Reply 5; Par CA3 Br. 57 & n.22; see *ZF Meritor*, 696 F.3d at 286–87 (Eaton had contracts with “every direct purchaser”); *Dentsply*, 399 F.3d at 195–96 (Dentsply’s exclusive distributors held “dominant position,” “leaving only a small sliver” for competitors); *LePage’s, Inc. v. 3M*, 324 F.3d 141, 160–61 & n.14 (3d Cir. 2003) (en banc) (3M all but entirely cut off rivals’ access to market).

<sup>13</sup> See Dkt. 170-18; Dkt. 170-19; Dkt. 170-21; Dkt. 170-22; Dkt. 170-23.

“not [] a practical alternative” and had “produced paltry results.” 399 F.3d at 189.

Similarly, in *LePage*’s, the court held that access to superstores was “necessary” to “compete profitably.” 324 F.3d at 160. Here, in contrast, Fresenius has not shown that access to BCN, Bachem, or PolyPeptide was “necessary” to competition. Just the opposite: [REDACTED] Topics E, O, P

[REDACTED] Dkt.

154-1 ¶¶ 374–75; *see* CA3 Op. 6. [REDACTED] Topics E, O, P

[REDACTED] Dkt. 154-1 ¶¶ 378–80, 388; *see* CA3

Op. 6 n.4. Alternatives were not just “practical”—they were *proven*.<sup>14</sup>

[REDACTED] Topic I

[REDACTED] Par SJ Reply 9–11. Unlike the plaintiff in *ZF Meritor*, which addressed “whether foreclosure of the market could be attributed to factors other than” the defendant’s contracts, 696 F.3d at 290, [REDACTED] Topic I

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<sup>14</sup> Fresenius may cite *Geneva Pharmaceuticals Technology Corp. v. Barr Laboratories Inc.*, 386 F.3d 485 (2d Cir. 2004), but that case underscores Fresenius’s failures here. The Second Circuit emphasized that Geneva’s claims “depend[ed] on its theory” that the defendants had a “monopoly” on the API. *Id.* at 492. Geneva survived summary judgment *only* because it was able to demonstrate a genuine issue with respect to the defendants’ power in the API market. *Id.* at 501–04.

Fresenius’s “speculation [and] conjecture do[] not create a material factual dispute.” *Robertson v. Allied Signal, Inc.*, 914 F.2d 360, 382 n.12 (3d Cir. 1990).

Finally, Fresenius may argue that “foreclosure of one competitor”—itself—“is sufficient.” FK CA3 Reply 27. This is incorrect as a matter of law under long-standing Third Circuit precedent. Antitrust law distinguishes between harm to competition and harm to the plaintiff; even assuming Par caused “harm to [Fresenius’s] business,” that “does not equal harm to competition.” *See Phila. Taxi Ass’n v. Uber Techs., Inc.*, 886 F.3d 332, 344 (3d Cir. 2018). Exclusive dealing may “disadvantage rivals,” *ZF Meritor*, 696 F.3d at 271, or even exclude “one or even several competitors,” *Roland Mach. Co. v. Dresser Indus., Inc.*, 749 F.2d 380, 394 (7th Cir. 1984), but it is not unlawful unless it forecloses competition generally, *Dentsply*, 399 F.3d at 187. Fresenius’s contrary argument would obliterate this fundamental rule, effectively writing the foreclosure requirement out of the law.

This Court should reject Fresenius’s unprecedented foreclosure theory and grant summary judgment in favor of Par.

### **C. There Is No Genuine Dispute As To Lack Of Causation.**

In addition to antitrust injury and substantial foreclosure, Fresenius fails to raise a genuine dispute as to lack of causation. The Third Circuit held that “where a valid patent independently blocks the plaintiff’s entry into the relevant market,

the defendant’s allegedly anticompetitive conduct cannot be the cause of the plaintiff’s injury.” CA3 Op. 9. This may require a court to “consider the substance” of the parties’ patent arguments—but only if, at a threshold matter, it finds that “the record permits . . . such an analysis.” *Id.* at 9–10. The record here does not.

Even if the record were sufficient to permit *Wellbutrin* scrutiny, Fresenius could not establish causation. Fresenius must show there is no genuine dispute that it would have avoided infringement of Par’s patents or that it would have overcome the presumption of validity by clear and convincing evidence. *See Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1378 (Fed. Cir. 2005). But Fresenius offers only conclusory arguments via fundamentally flawed expert opinions. That paltry and legally deficient showing cannot defeat summary judgment.

**1. The Record Does Not Allow For A *Wellbutrin* Analysis Because Fresenius’s ANDA Product Is Speculative.**

A legally sufficient infringement analysis requires “knowledge of the accused product[.]” *Lava Trading, Inc. v. Sonic Trading Mgmt., LLC*, 445 F.3d 1348, 1350 (Fed. Cir. 2006). **Topics A, F, H**

**Topics A, F, H**. Though “the absence of a filed ANDA” is not determinative, CA3 Op. 9 n.9, that does *not* mean Fresenius **Topics A, F, H**

**Topics A, F, H** Rather, the Third Circuit recognized that “ambiguities in what the proposed ANDA would have contained” may “absolve” this Court of performing a *Wellbutrin* analysis. *Id.*

**Topics A, F, H**

As this Court rightly observed, there is no “draft ANDA, or other elements which would have been in the But For ANDA, such as the testing specifications for excipients; drug product specifications; quality overall summary of the product; clinical study reports; or documents on bioequivalences to the reference listed drug.” Dkt. 240 at 10. Simply put, the evidence provides no indication what “the proposed ANDA” would have looked like. CA3 Op. 9 n.9.

In the real world, **Topics A, F, H, K**

<sup>16</sup> **Topics A, F, H, K**

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<sup>15</sup> See FK CA3 Br. 8 (“**Topics A, F**”); Dkt. 201-07 at 185:12–15 (“**Topics A, F**”).

<sup>16</sup> Dkt. 152-40 ¶¶ 1168, 1175, 1180, 1188.

**Topics A, F, H, K**

. See Par CA3 Br. 38–39. None. **Topics A, F, H, K**

**Topics A, F, H, K**

Dkt.

184-38.<sup>18</sup> This is precisely the type of deficient record that, under the Third Circuit’s decision in this case, “absolve[s]” this Court of any need to conduct a full-some *Wellbutrin* analysis. CA3 Op. 9 n.9.<sup>19</sup> Fresenius has failed to create a genuine issue of material fact, and summary judgment is warranted.

**2. Even Under A *Wellbutrin* Analysis, Dr. Tarantino’s Non-Infringement Opinions Are Fundamentally Flawed.**

As shown above, this Court can grant summary judgment for Par without a

<sup>17</sup> See Par SJ Br. 45–46; Par SJ Reply 19; Par CA3 Br. 38–39.

<sup>18</sup> As explained in Par’s Third Circuit brief, **Topics A, F**

Dkt. 184-34 ¶¶ 3, 16; see Par CA3 Br. 38. **Topics A, F**  
**Topics A, F** Par CA3 Br. 38.

<sup>19</sup> See *Berrada v. Cohen*, 2018 WL 4629569, at \*4 (D.N.J. Sept. 26, 2018) (Wigenton, J.) (“self-serving testimony” does not create a genuine dispute), *aff’d*, 792 F. App’x 158 (3d Cir. 2019); *Blair v. Scott Specialty Gases*, 283 F.3d 595, 608 (3d Cir. 2002) (“conclusory, self-serving affidavits” cannot defeat summary judgment).

full *Wellbutrin* analysis. But even considering the substance of its patent arguments, Fresenius has failed to demonstrate a genuine issue of material fact on the element of causation. Beginning with infringement: Dr. Tarantino’s non-infringement opinion is fundamentally flawed and cannot withstand summary judgment as a matter of law, **Topic K**

**Topic K**.<sup>20</sup>

Fresenius tries to excuse this gaping omission by claiming it is Par’s burden to prove infringement in a patent case. But this is an *antitrust* case, and as *Wellbutrin* instructs, it is *Fresenius’s* burden to prove causation— **Topics A, F, K**

**Topic K**. 868 F.3d at 165–66.

That’s not all: **Topics A, F, K**

**Topic K**

<sup>21</sup> **Topics A, F, K**

**Topic K**

**Topic K**. Dkt. 183-41 ¶ 1169. **Topics A, F, K**

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<sup>20</sup> Dkt. 183-44 ¶¶ 249–53; Dkt. 172-19 at 153:24–154:12; *see Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1298 (Fed. Cir. 2009) (en banc).

<sup>21</sup> Dkt. 152-40 ¶¶ 1169–72; Dkt. No 172-22 ¶¶ 127–29. Fresenius argues that because Par agreed not to sue Fresenius on the ’239 patent, Par cannot show that the ’239 patent bars Fresenius’s antitrust claims. FK CA3 Reply 13. This argument is frivolous: **Topics A, F, I, K**

has no bearing on whether, in the but-for world, the ’239 patent would have independently barred Fresenius’s market entry.

## Topics A, F, K

. Dkt. 170-35 ¶¶ 273–90; *see AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010). Contrary to Fresenius’s argument, this issue can and should be resolved on summary judgment.<sup>22</sup>

This Court should reject Fresenius’s non-infringement argument because there is no cognizable evidence of Fresenius’s hypothetical product, and Dr. Tarantino’s flawed non-infringement opinions do not create a genuine dispute.

### 3. Fresenius Has Not Presented Any Cognizable Evidence That Par’s Patents Are Invalid.

Fresenius relies on Dr. Tarantino to argue that Par’s patents would have been found invalid for obviousness in the but-for world. On its face, Dr. Tarantino’s analysis is legally deficient. Obviousness requires proof that at the time of the invention, a POSA would have been motivated to combine the teachings of prior art to arrive at the invention with a reasonable expectation of success. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068–69 (Fed. Cir. 2012). Fresenius must *start with* the prior art, and show that it would have led a POSA to the invention. *See Monarch Knitting Mach. Corp. v.*

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<sup>22</sup> Par CA3 Br. 41; *see, e.g., EKR Therapeutics, Inc. v. Sun Pharm. Indus., Ltd.*, 633 F. Supp. 2d 187, 202–03 (D.N.J. 2009) (granting summary judgment to patent holder where ANDA filer’s label directed doctors to infringe).



*Sulzer Morat GmbH*, 139 F.3d 877, 881–82 (Fed. Cir. 1998). “Defining the problem in terms of its solution”—that is, as disclosed in the patent itself—“reveals improper hindsight in the selection of prior art relevant to obviousness.” *Id.* at 881.

## Topic K

Dkt. 152-40 ¶ 350,

## Topic K

Dkt. 172-43 ¶ 41; *see* Dkt. 152-40 ¶ 351. This is *per se* legal error and “infect[s]” Dr. Tarantino’s entire obviousness analysis. *Monarch Knitting*, 139 F.3d at 881–82. Dr. Tarantino’s flawed opinions could not support a verdict for Fresenius.<sup>23</sup>

Fresenius will presumably argue that Dr. Tarantino’s opinions, no matter how legally deficient, are sufficient to create an issue of fact as to patent validity, leaving the issue to be resolved by a jury. Wrong. Courts routinely resolve validity challenges on summary judgment even where the party challenging the presumption of validity submits an expert opinion that the patent is invalid.<sup>24</sup>

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<sup>23</sup> *See Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1377–80 (Fed. Cir. 2012) (vacating obviousness ruling where district court “used the invention to define the problem that the invention solves,” **Topic K**).

<sup>24</sup> *E.g., Valeant Pharms. Int’l, Inc. v. Mylan Pharms., Inc.*, No. 15-8180, Dkt. 300 (D.N.J. May 1, 2018); *Merck & Co., Inc. v. Sandoz Inc.*, No. 10-1625, Dkt. 143 (D.N.J. Jan. 30, 2012); *Waddington N. Am. v. Sabert Corp.*, No. 09-4883, Dkt. 181 (D.N.J. Mar. 22, 2011); *Janssen Pharms. v. Watson Labs., Inc.*, No. 08-5103, Dkt. 168 (D.N.J. Jan. 25, 2011).

#### 4. Fresenius's Litigation Predictions Are Speculative.

Fresenius argues that *Wellbutrin* requires this Court not only to consider, but to *rely upon*, experts' predictions of hypothetical litigation outcomes. FK CA3 Br. 26–27, 42. Not so. In *Wellbutrin*, the Third Circuit disregarded litigation-prediction testimony that was unsupported. 868 F.3d at 169. Here, the Third Circuit recognized that there may be “grounds to reject” Fresenius's experts. CA3 Op. 9 n.8.

There are “grounds to reject” the speculative litigation predictions of Professor Thomas, who opines that— **Topic K**

Dkt. 172-22

¶¶ 103–65.<sup>25</sup>

**Topic K**

. Dkt. 172-23 ¶ 25.

**Topic K**

Dkt. 172-20 at 70:25–71:16. An expert's “theoretical speculations” cannot defeat summary judgment. *Pa. Dental Ass'n v. Med. Serv. Ass'n of Pa.*, 745 F.3d 248, 262 (3d Cir. 1984). The Court should disregard Professor Thomas's factually unsupported and speculative testimony.

#### IV. CONCLUSION

For these reasons, the Court should grant summary judgment for Par.

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**Topic K**

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By: /s/ Thomas R. Curtin

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